



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,439	01/05/2007	Bruno Lussier	09555.0151USWO	4659
23552	7590	07/08/2010	EXAMINER	
MERCHANT & GOULD PC			BRADLEY, CHRISTINA	
P.O. BOX 2903				
MINNEAPOLIS, MN 55402-0903			ART UNIT	PAPER NUMBER
			1654	
			MAIL DATE	DELIVERY MODE
			07/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,439	LUSSIER ET AL.	
	Examiner	Art Unit	
	CHRISTINA BRADLEY	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 May 2010.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 3-14 and 16-24 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 3-14 and 16-24 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>05/04/2010</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

DETAILED ACTION

Status of the Claims

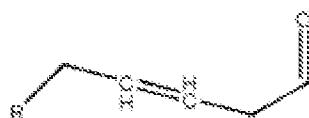
1. Applicant's election of the species (hexenoyl trans-3)hGRF(1-44)NH₂ and the species chronic obstructive pulmonary disease in the reply filed on 11/24/2009 is acknowledged. Because the search of the species yielded prior art on the full genus of GRF analogs, the election of species requirement mailed 10/27/2009 is withdrawn.
2. Claims 3-14 and 16-24 are pending.

Claim Objections

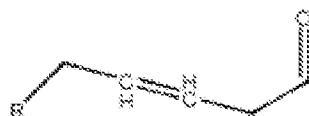
3. Claims 3-6, 8-14 and 16-24 are objected to for the limitation in claim 3 "the hydrophobic tail defining a backbone of 5 to 7 atoms". The word "defining" should be replaced with a word that explicitly describes the structure of the hydrophobic tail and its backbone.
4. Claim 4 is objected to because of the use of parenthetical phrases used to define variables in the chemical structures set forth in the claim. Definitions for each variable must be explicitly included in the claim. In addition, enantiomers and racemic mixtures must be clearly claimed.

An acceptable format for the claim would be

...wherein X is



wherein R is H, CH₃ or CH₂CH₃, and the double bond is *cis* or *trans*;



wherein R is H, CH₃ or CH₂CH₃;....

5. In addition claim4 is objected to because it does not end in a period.

Claim Rejections - 35 USC § 102 - withdrawn

6. The rejection of claims 3-6, 8-14, 22-24 and 74-79 under 35 U.S.C. 102(b) as being anticipated by Gravel et al. (US 6,458,764) is withdrawn in light of the amendment filed 05/04/2010. Gravel et al. do not teach administration of GRF analogs to subjects suffering from wasting.

7. The rejection of claims 3-14, 22-24 and 74-80 under 35 U.S.C. 102(b) as being anticipated by Larocque et al. ("Anchoring rigid hydrophobic chains to stabilize growth hormone-releasing factor," APS Poster, 2001) is withdrawn in light of the amendment filed 05/04/2010. Larocque et al. do not teach administration of a GRF analog to subjects suffering from wasting. The statement at the conclusion of the poster that the GRF analog TH9507 (instant SEQ ID NO: 7) is being used to stimulate anabolism in COPD patients does not anticipate the instant claims because a COPD patient does not necessarily suffer from wasting, as evidenced by Debigare et al. ("Peripheral Muscle Wasting in Chronic Obstructive Pulmonary Disease," Am. J. Respir. Crit. Care Med., Volume 164, Number 9, November 2001, 1712-1717, especially p. 1712).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Upon further consideration, a new ground(s) of rejection is made in view of references cited on the IDS mailed 05/04/2009.

10. Claims 3-14, 16, 23 and 24 are rejected under 35 U.S.C. 102(a) as being anticipated by “Theratechnologies completes patient enrollment for its clinical study on chronic obstructive pulmonary disease as part of its phase II program on ThGRF,” online, April 23, 2003, (hereafter the press release of April 23, 2003). The press release of April 23, 2003 discloses a clinical trial in which 1 or 2 mg of ThGRF are administered to patients suffering from COPD-associated wasting. ThGRF is an alternative name for the GRF analog of instant claim 7 (SEQ ID NO: 7).

11. Claims 3-14, 16, 23 and 24 are rejected under 35 U.S.C. 102(a) as being anticipated by “Theratechnologies: patient enrollment completed in hip fracture phase II clinical for ThGRF,” online, July 9, 2003, (hereafter the press release of July 9, 2003). The press release of July 9, 2003 discloses a clinical trial in which 2 mg of ThGRF are administered to patients suffering from wasting following hip fracture. ThGRF is an alternative name for the GRF analog of instant claim 7 (SEQ ID NO: 7).

12. Claims 3-14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by “Theratechnologies and Saki Chemicals in landmark licensing agreement to develop and market ThGRF peptide in Japan,” online, February 5, 2002 (hereafter the press release of February 5, 2002). The press release of February 5, 2002 states on p. 2 that Theratechnologies has launched clinical trials on ThGRF for indications such as muscle wasting observed in chronic obstructive

pulmonary disease and hip fractures, as well as sleep maintenance insomnia and certain immune system dysfunctions in the elderly. ThGRF is an alternative name for the GRF analog of instant claim 7 (SEQ ID NO: 7).

13. Claims 3-14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by “Theratechnologies announce positive results of an efficacy and safety phase II clinical trial of ThGRF in sleep maintenance insomnia,” online, May 29, 2002 (hereafter the press release of May 29, 2002). The press release of May 29, 2002 states that Theratechnologies has launched clinical trials on ThGRF for indications such as muscle wasting observed in chronic obstructive pulmonary disease and hip fractures, as well as sleep maintenance insomnia and certain immune system dysfunctions in the elderly. ThGRF is an alternative name for the GRF analog of instant claim 7 (SEQ ID NO: 7).

14. Claims 3-14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by “Theratechnologies clinically demonstrates improvement in immune function among elderly with ThGRF peptide,” online, June 6, 2002 (hereafter the press release of June 6, 2002). The press release of June 6, 2002 on p. 2 states that Theratechnologies has launched clinical trials on ThGRF for indications such as muscle wasting observed in chronic obstructive pulmonary disease and hip fractures, as well as sleep maintenance insomnia and certain immune system dysfunctions in the elderly. ThGRF is an alternative name for the GRF analog of instant claim 7 (SEQ ID NO: 7).

15. The press releases cited above do not explicitly teach the effect of ThGRF on muscle function in patients suffering from wasting. Because the press preleases teach that the same

compound was administered to the same patient population as the instant invention, the effect on muscle function is inherently met.

Claim Rejections - 35 USC § 103 - Withdrawn

16. The rejection of claims 50-55 under 35 U.S.C. 103(a) as being unpatentable over Gravel et al. (US 6,458,764) is moot because the claims are cancelled.

17. The rejection of claims 50-56 under 35 U.S.C. 103(a) as being unpatentable over Larocque et al. is moot because the claims are cancelled.

18. The rejection of claims 50-56 under 35 U.S.C. 103(a) as being obvious over US 7,316,997 **OR** US 20090011985 **OR** US20090253623 **OR** US 20090088383 is moot because the claims are cancelled.

19. The rejection of claims 15-21 under 35 U.S.C. 103(a) as being unpatentable over US 7,316,977 **OR** US 20090011985 **OR** US20090253623 **OR** US 20090088383 in view of Schwartz et al. is withdrawn. Applicant has provided evidence in this file (see p. 15 of the response filed 05/04/2010) showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as 7,316,977, US 20090011985, US20090253623 and US 20090088383 at the time this invention was made. Therefore, these references are disqualified as prior art under 35 U.S.C. 103(c).

20. The rejection of claims 15-21 under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (US 6,423,693) in view of Larocque et al. (“Anchoring rigid hydrophobic chains to stabilize growth hormone-releasing factor,” APS Poster, 2001) is withdrawn.

It is *prima facie* case obviousness to substitute the GRF analog SEQ ID NO: 7 of Larocque et al. for the gene therapy approach in the method of delivering GHRH to wasting patients in Schwartz et al. However, Applicants have demonstrated unexpected results which are sufficient to overcome the *prima facie* case.

As stated by Applicant on pp. 12-13 of the response filed 05/04/2010, the prior art of Schwartz et al. and Larocque et al. does not address the effect of GHRH on muscle function in a patient suffering from wasting. In contrast, Schwartz et al. reasons that based on the known effects of growth hormone on muscle mass, GHRH, which stimulates growth hormone, could be used to treat wasting. On p. 13-14 of the response filed 05/04/2010, Applicants present evidence that an increase in muscle mass following growth hormone administration does not correlate with an increase in muscle function (see Zachwieja & Yarasheski, Lissett & Shalet, Burdet et al. and Pape et al. Appendix A-D filed 05/04/2010). In contrast, the inventors have shown in a randomized, double-blind, placebo-controlled study, that administration of SEQ ID NO: 7 to subjects with stable COPD increases muscle function and muscle mass (see Example 6 of the original specification, especially Table 2 which shows that the Low BMI and Low FFMI groups, which suffer from severe wasting, exhibit an increase in muscle function in response to SEQ ID NO: 7 as compared to placebo). The effect of SEQ ID NO: 7 on muscle function in patients suffering from wasting could not have been predicted from Schwartz et al. and Larocque et al., as evidenced by Zachwieja & Yarasheski, Lissett & Shalet, Burdet et al. and Pape et al.

Furthermore, it is clear from the prior art of Burdet et al. that an increase in muscle function is a desired clinical outcome for wasting patients and a goal for research in this field (see p. 1800).

21. MPEP § 716.02(c) states: “Evidence of unexpected results must be weighed against evidence supporting *prima facie* obviousness in making a final determination of the obviousness of the claimed invention. *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (Claims directed to a method of effecting analgesia without producing physical dependence by administering the levo isomer of a compound having a certain chemical structure were rejected as obvious over the prior art. Evidence that the compound was unexpectedly nonaddictive was sufficient to overcome the obviousness rejection. Although the compound also had the expected result of potent analgesia, there was evidence of record showing that the goal of research in this area was to produce an analgesic compound which was nonaddictive, enhancing the evidentiary value of the showing of nonaddictiveness as an indicia of nonobviousness.).” The facts of the instant case are similar to the facts of *In re May*. Although SEQ ID NO: 7 has the expected result of increasing muscle mass in wasting patients, it also has the unexpected result of increasing muscle function. Thus, the value of the unexpected result must be weighed against the value of the expected result. Because there is evidence of record in both in the instant specification and in Burdet et al. showing that the goal of research in this area was to increase muscle function in wasting patients, this unexpected property of SEQ ID NO: 7 outweighs the *prima facie* case for obviousness.

Claim Rejections - 35 USC § 103 - maintained

Art Unit: 1654

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 3-6, 8-14 and 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (US 6,423,693) in view of Gravel et al. (US 6,458,764).

24. Schwartz et al. teach that growth hormone releasing hormone (GHRH) has therapeutic utility in stimulating the production and secretion of growth hormone (GH) (col 2, lines 30-37) and specifically in the treatment of cachexia in chronic diseases such as cancer (col 2, lines 38-48, col 34, line 44 - col 35, line 18) and the treatment of chronic obstructive pulmonary disorder (col 11, lines 55-65). Schwartz et al. teaches that current limitations of recombinant GHRH therapy include the short half-life of the peptides in vivo and the requirement for frequent administration (1-3 times/day) of either subcutaneous or intravenous injections (col 2, lines 49-57). Schwartz et al. propose as an alternative to administration of GHRH peptides, a gene-therapy approach to circumvent these limitations.

Schwartz et al. do teach a method of administering GRF analogs of formula A.

Gravel et al. teach GRF analogs of formula A which is identical to the formula in instant claim 3. Gravel et al. teach that the analogs have improved biological potency and prolonged activity, increased anabolic potency and prolonged activity, i.e. capable to substantially elevate insulin-like growth factor I (IGF-I) levels when chronically administered in humans and animals (col 4, lines 34-48).

It would have been obvious to one of ordinary skill in the art to use the GFR analogs of formula A taught by Gravel et al. in the method of treating wasting and COPD taught by Schwartz et al. The skilled artisan would have been motivated to do so given that Gravel et al. teach that the GRF analogs have improved potency and prolonged activity which overcomes the disadvantages with GRF therapy identified by Schwartz et al. There would have been a reasonable expectation of success given that Gravel et al. administer the GRF analogs of formula A to animals and that they exhibit an ability to induce GH secretion (Examples 3 and 4). With respect to claim 17-21, Schwartz et al. do not teach the specific criteria for diagnosing patients with wasting (i.e. BMI, fat-free mass index and ideal weight). It would have been obvious to select patients with severe wasting because such patients would be most in need of therapy.. With respect to claims 22-24, Gravel et al. teach subcutaneous injection of 20 µg/kg of body weight (Example II) which falls within the claimed range of about 1 to 2 mg for an average adult human.

Applicant's assertion of unexpected results in the response filed 05/04/2010 (discussed above) is insufficient to overcome the *prima facie* case of obviousness over Schwartz et al. and Gravel et al. MPEP § 716.02(c) states: "Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence

of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support.' In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980)." In the instant case, the unexpected results presented in the instant specification pertain only to a single species (SEQ ID NO: 7) of the claimed genus formula A. Given the structural diversity of the GRF analogues in Formula A, data on the effect of SEQ ID NO: 7 on muscle function is not representative of the effect of the full genus of GRF analogues on muscle function. Only claim 7 which is limited to SEQ ID NO: 7 is nonobvious over Schwartz et al. and Gravel et al.

Double Patenting - Withdrawn

25. The rejection of claims 3-14, 22-24, 50-56 and 74-80 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,316,997 is withdrawn in light of the amendment filed 05/04/2010.

26. The provisional rejection of claims 3-14, 22-24, 50-56 and 74-80 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-88 of copending Application No. 12/239,697 **OR** claims 1-88 of copending Application No. 12/239,708 **OR** claims 1-88 of copending Application No. 12/239,712 is withdrawn in light of the amendment filed 05/04/2010.

27. The rejection of claims 15-21 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,316,997 in view of Schwartz et al. is withdrawn. Applicant's showing of unexpected results overcomes the *prima facie* case of obviousness for the reasons presented above.

Double Patenting - maintained

28. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

29. Claims 3-6, 8-14 and 16-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-34 and 89-104 of copending Application No. 11/877,395 **OR** claims 1-88 of copending Application No. 12/239,697 **OR** claims 1-88 of copending Application No. 12/239,708 **OR** claims 1-88 of copending Application No. 12/239,712, as applied to claims 3-14, 22-24, 50-56 and 74-80 above, in further view of

Schwartz et al. (US 6,423,693). An independent rejection is made over each of these copending applications but because the rejections are substantially identical they are presented in consolidated form for the sake of brevity. Although the conflicting claims are not identical, they are not patentably distinct from each other.

30. Claim 1 of copending Application No. 11/877,395 recites a method of administering GRF analogues of formula A, identical to the genus in instant claim 3.

31. Claim 90 of copending Application No. 12/239,697 recites a method of administering GRF analogues of formula A, identical to the genus in instant claim 3.

32. Claim 3 of copending Application No. 12/239,712 recites a method of administering GRF analogues of formula A, identical to the genus in instant claim 3.

33. The claims do not teach a method of administering GRF analogs to patients with wasting.

Schwartz et al. teach that growth hormone releasing hormone (GHRH) has therapeutic utility in stimulating the production and secretion of growth hormone (GH) (col 2, lines 30-37) and specifically in the treatment of cachexia in chronic diseases such as cancer (col 2, lines 38-48, col 34, line 44 - col 35, line 18) and the treatment of chronic obstructive pulmonary disorder (col 11, lines 55-65). Schwartz et al. teaches that current limitations of recombinant GHRH therapy include the short half-life of the peptides in vivo and the requirement for frequent administration (1-3 times/day) of either subcutaneous or intravenous injections (col 2, lines 49-57). Schwartz et al. propose as an alternative to administration of GHRH peptides, a gene-therapy approach to circumvent these limitations.

It would have been obvious to one of ordinary skill in the art to use the GFR analog claimed in the copending applications cited here in the method of treating wasting and COPD

Art Unit: 1654

taught by Schwartz et al. The skilled artisan would have been motivated to do so given that the copending applications indicate that the GRF analog is suitable for therapeutic use, suggesting that it has overcome the disadvantages with GRF therapy identified by Schwartz et al. With respect to claim 17-21, Schwartz et al. do not teach the specific criteria for diagnosing patients with wasting (i.e. BMI, fat-free mass index and ideal weight). It would have been obvious to select patients with severe wasting because said patients are most in need of treatment. With respect to claims 22-24, the copending applications cited here claims methods of subcutaneous administration of dosages equal to about 1 or 2 mg.

The *prima facie* case of obvious is not overcome by Applicant's showing of unexpected results because the results which pertain only to SEQ ID NO: 7 are not commensurate in scope with the full genus of GRF analogues. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

34. The following claim drafted by the examiner and considered to distinguish patentably over the art of record in this application, is presented to applicant for consideration:

A method of increasing muscle function in a subject suffering from severe wasting comprising administering to said subject the GRF analog (hexenoyl trans-3)hGRF(1-44)NH₂ (SEQ ID NO: 7), wherein

- (a) said subject has a body mass index less than or equal to 20;
- (b) said subject has a weight less than 90% of ideal body weight;

(c) said subject is a male and said subject has a fat free mass index less than or equal to 16; or

(d) said subject is a female and said subject has a fat free mass index less than or equal to 15.

The press releases cited in the anticipation rejections above to do not teach the administration of ThGRF to patients suffering from severe wasting and having the diagnostic criteria listed in parts (a)-(d) of the proposed claim. A *prima facie* case of obviousness over the press releases in view of prior art pertaining to severe wasting would be overcome by the unexpected results presented in the response filed 05/04/2010 and in the original specification.

Applicant is invited to contact the Examiner upon receipt of this Office action to discuss this proposed claim and to resolve outstanding issues in this Application.

Conclusion

35. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA BRADLEY whose telephone number is (571)272-9044. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 8:30 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christina Marchetti Bradley/
Examiner, Art Unit 1654

cmb